



# UNITED STATES PATENT AND TRADEMARK OFFICE

*ch*  
UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/673,617	01/25/2001	Kim Sorensen	030307/0191	2002
22428 7590 01/11/2007 FOLEY AND LARDNER LLP SUITE 500 3000 K STREET NW WASHINGTON, DC 20007			EXAMINER BURKHART, MICHAEL D	
			ART UNIT	PAPER NUMBER
			1633	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		01/11/2007	PAPER	

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	<b>Application No.</b> 09/673,617	<b>Applicant(s)</b> SORENSEN ET AL.	
	<b>Examiner</b> Michael D. Burkhart	<b>Art Unit</b> 1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 21 July 2006 and 26 October 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 43-53 and 55-70 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 43, 44, 46-49, 51-53, 56, 58, 59, 61, 63, 64, 66, 68 and 69 is/are allowed.
- 6) ☒ Claim(s) 45, 50, 57, 60, 62, 65, 67 and 70 is/are rejected.
- 7) ☒ Claim(s) 55 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

Receipt of the responses dated 7/21/2006 and 10/26/2006 is acknowledged. After entry of the 10/26/2006 amendment, claims 43-53, 55-70 are pending and under examination.

#### ***Claim Objections***

Claim 55 is objected to because of the following informalities: "auxothropic" in line 3 should be "auxotrophic". Appropriate correction is required.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 50, 60, 65, and 70 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 50 recites a vector that, in line 7, lacks a gene for antibiotic resistance, but also comprises a gene for nisin (an antibiotic) resistance (line 8). It is unclear how the claimed vector can have both properties, therefore the metes and bounds of the claimed subject matter are unclear. This rejection affects all dependent claims.

#### ***Response to Arguments***

Applicant's arguments filed 7/21/2006 have been fully considered but they are not persuasive. Applicants assert that nisin is a bacteriocin, not an antibiotic, hence the claims are not indefinite. However, absent evidence to the contrary, a bacteriocin is an antibiotic, i.e. "An

Art Unit: 1633

antibiotic produced by bacteria" (Source: *Merriam-Webster's Medical Dictionary*. Merriam-Webster, Inc., 2002). Therefore, the claims remain indefinite.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 45, 57, 62 and 67 are rejected under 35 U.S.C. 102(b) as being anticipated by Dickely et al (Mol. Micro., 1995). This rejection is maintained for reasons of record (as applied to claims 1-4, 7, 9-14, 16, 17, 22-25, 28-29, 31-33, 36-38, 40 and 42 in the Office Actions of 6/30/2004 and 7/13/2005) and for reasons set forth below.

Regarding new claims 57, 62, and 67, Dickely et al teach in the course of producing the pFG1 vector, bacterial transformants (i.e. the lactic acid bacterium DN209) containing the vector were isolated by plating and culturing (page 843, first column and page 845, first column). Absent a definition in the specification a carrier is considered to be any media component, i.e. agar or liquid media.

### ***Response to Arguments***

Applicant's arguments filed 7/21/2006 have been fully considered but they are not persuasive. Applicants assert that the instant claims now encompass the subject matter of canceled claim 8, not previously rejected over Dickely et al. This is not convincing, because the

Art Unit: 1633

instant claims merely recite a product (an amber (CUA) suppressor tRNA) by process, i.e. a CUA suppressor tRNA that arises in a host cell by mutation of two or three changes of nucleotide in the anticodon region of a tRNA gene. See MPEP §2113:

"Product-by-process claims are not limited to the manipulations of the recited steps, only the structure implied by the steps."

The fact remains that the end product must be an amber suppressor, i.e. it must have a CUA codon (see page 839, second column, first full ¶ of Dickely et al). This is not even a process the skilled artisan can perform, but is rather a function of the host cell itself. Therefore, because Dickely teaches an amber suppressor tRNA, along with the remaining claim limitations, the claims are anticipated by Dickely et al regardless of how the amber suppressor tRNA taught by Dickely was produced by the host cell.

### ***Conclusion***

Claims 43-44, 46-49, 51-53, 56, 58, 59, 61, 63, 64, 66, 68, and 69 are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

Art Unit: 1633

will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

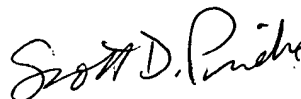
however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael D. Burkhart whose telephone number is (571) 272-2915. The examiner can normally be reached on M-F 8AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Michael D. Burkhart  
Examiner  
Art Unit 1633



**SCOTT D. PRIEBE, PH.D**  
**PRIMARY EXAMINER**